



CHAIN WHOLE STOOL COLLECTION SOP

CHN ...: CHAIN WHOLE STOOL COLLECTION SOP

Purpose

The purpose of this SOP is to describe the standard procedures involved in collection and transport to the laboratory of study whole stool samples.

Responsibility

This SOP applies to nursing staff, study clinicians and fieldworkers of study sites who will be undertaking the collection of whole stool samples. It is the responsibility of the users to follow the guidelines stipulated herein.

The Principal Investigator (through the study coordinator when applicable) retains the overall responsibility of implementation of these standard procedures.

The study laboratory coordinator is responsible for answering questions you may have about the content of this SOP and any other relevant study documentation. Please contact the study laboratory coordinator through your site coordinator.

Laboratory coordinator: [Caroline Tigoi](#) Email: ctigoi@kemri-wellcome.org

Abbreviations/Definitions

SOP	Standard Operating Procedure
PID labels	Positive Identification Labels
CHN	CHAIN

Required material

- Clean stool specimen container for stool with spoon attached to lid
- Cling-film/disposable plastic diapers/ disposable diapers
- Pens/ markers
- Biohazard bins and bags (red autoclavable or equivalent)
- Gloves (disposable)
- PID labels
- Plastic bags (zip lock) for specimen transport
- Ice packs (reusable)
- Shipping/ Mailing containers/ cool box for specimen shipment
- Small clean dry plastic bags for specimen collection in clinic (if necessary)
- Paper towels/ tissue rolls or equivalent

CHAIN WHOLE STOOL COLLECTION SOP

Methods

1.0 General considerations

- 1.1 Consult the Sample Collection Schedule (appendix) prior to each collection.
- 1.2 Wear proper protective equipment, lab coats, and gloves.
- 1.3 Appropriate collection devices, specimen containers, must be used to ensure optimal recovery of microorganisms and storage.
- 1.4 Sufficient quantities of specimens must be obtained in order to perform all tests requested but, if quantities are insufficient, specimen will still be used for priority tests.
- 1.5 Personnel are responsible for collecting specimens and devices in proper containers such as biological waste bags in biohazard bins. The biohazard waste must then be autoclaved and/ or incinerated.
- 1.6 Handle all specimens with care and treat them as potentially infectious material.
- 1.7 All should be shipped in containers labelled with biohazard symbol at any given time.
- 1.8 The following time limits are applicable:
 - 1.8.1 Admission sample: Collect rectal swabs immediately (see Rectal Swab Collection SOP (CHN..)). If the child passes stool during swabbing, collect it as the admission sample. The child will be in the fetal position, and stool can be collected directly into the collection cup either using the scoop, or by holding the cup at the anus.
 - 1.8.2 If they don't pass stool during rectal swabbing, collect the first stool the child passes after admission. An admission stool sample will be any first successfully collected sample. The child should wear a well-fitting inverted disposable diaper based on the child's size during admission to allow stool collection. Aim to obtain the stool during working hours so the sample can be processed immediately. If no sample obtained during the day, as a last resort, the mother shall be given a well labelled clean stool collection container with spoon attached to the lid overnight to collect stool if it happens during the night and instructed to place the stool sample in a cool box with ice packs/fridge. The caregiver should be trained on how to scrape the stool from the diaper into the stool container using the spoon attached to the lid. Date and time of stool production must be recorded carefully on the enrolment form and the CRF.
 - 1.8.3 Discharge sample: If the nursing staff believe the patient is improving and will be discharged, ensure that the child wears a well-fitting inverted disposable diaper. The caregiver maybe left overnight with a clean stool collection container with spoon attached to the lid to collect next stool sample and instructed to place the stool sample in cool box with ice packs/fridge. Recorded collection time and date on the CRF. If another sample is collected closer to discharge or during the rectal swab, the site shall retain the most current sample and carefully document the dates and times that each sample was collected on a blank new CRF and sample transportation log. Make aliquots of the stools and Label them as D01, D02 or D03, then store them temporarily in -80 degrees freezer until the child is discharged. Update the database to include the sample collected closest to discharge date with CHAIN ID, discard the ones collected earlier, then store them sample in a -80°C freezer. If the child is ready to leave the hospital (i.e. all clinical and study procedures have been completed) but no whole stool sample has been collected, you should not delay the family for longer than 2 hours in order to collect this stool sample. If the fieldworker will be doing the home assessment

CHAIN WHOLE STOOL COLLECTION SOP

on the same day as discharge, give them a labelled stool collection container with a cool box with ice to collect the sample at home just in case the child passes stool. If the fieldworker will be doing the home assessment on the same day as discharge, give them a labelled stool collection container with a cool box with ice to collect the sample at home just in case the child passes stool. You can also give the care giver a labelled fecal pot to take home and let them collect the stool and deliver to hospital within 4 hours of production. The window period for mother to collect a discharge stool sample after discharge date is 7 days but stool must be delivered to the clinic within 4 hours of production by the baby. If the sample is not collected by end of this time period, mark the stool sample as missing on the discharge CRF. Leave additional labeled pots with the care giver for them to collect stool in the morning before coming for the follow-up appointment visit. They should bring the stool to the clinic within 4 hours after production.

- 1.8.4 Follow-up samples: Remind the care giver a day before the scheduled visit to collect a stool sample in the morning before coming to the clinic on the appointment day and deliver it to hospital clinic within 4 hours of production. If the stool has not been collected already, collect rectal swabs immediately (see rectal swab SOP (CHN...)) upon presentation at clinic. Receive any stool sample brought to the clinic by the care giver and document clearly the time of production and delivery time at the clinic. If the child passes stool during swabbing collect this fresh sample as the follow up sample and discard the stools collected earlier at home. If no stool is passed during swabbing, ask the caregiver to collect the next available stool passed within 7 days post appointment date and deliver it to the clinic within 4 hours of production by the baby. If the family has completed all clinical and study procedures and has been at the clinic for longer than 3 hours after all other tests are complete you should not delay the family. You then wait for 7 days for the care giver to collect the stool and if stool is not collected them, them mark the stool sample as missing on the Follow up CRF.
- 1.8.5 At all-time points it is very important that you record the time at which stool samples were produced/collected to track the exact time stool has taken from production to delivery to hospital/lab. Transport all the stool samples immediately after collection/production to the lab for processing and storage. Record all the relevant information on the relevant CRFs.

2.0 Collection of whole stool sample

- 1.1 Label the stool specimen container with the Country code, site code, collection time point, (see Collection Schedule (appendix 7.2), specimen type (Stool), Patient ID and date of collection. For example: **PB-SAM-10-001-A0-F1-XXX-12/01/21**. Add a red sticker to the tubes if caregivers do not consent to international shipping of samples.
- 2.1 Explain the procedure to the caregiver.
- 2.2 Instruct the caregiver that if the child is able to produce stool, then a whole stool will be collected in addition to two rectal swabs for sites that are doing stool culture. The caregiver should inform the nurse or a member of the research team as soon as the child passes stool.
- 2.3 The study staff are to prepare a stool specimen cup, label the cup with the patient ID, and then follow the below procedure:

CHAIN WHOLE STOOL COLLECTION SOP

- 2.3.1 Cling-film, water resistant diapers or reversed nappies should be used to wrap the base of a well-fitting disposable diaper of an infant or toddler.
 - 2.3.2 Collect stool samples even if contaminated by urine, **do not** discard.
 - 2.3.3 Once the stool has been produced, the study staff will transfer the stool from the cling-film or inverted diaper into the stool specimen container using the plastic scoop on the inside of the lid of the stool collection container. The minimal volume is approximately 5ml or a teaspoon full
 - 2.3.4 Do not scrape the diaper lining as this will get diaper fibers in the sample. Ideally the sample should be collected from the cling-film lining the diaper or from an inverted diaper.
- 2.4 Collect as much stool as possible and place it in a cool box with ice packs.
- 2.5 Ideally, Stool samples should be transported to the laboratory within 30 minutes after collection in a cool box with ice packs, but do not discard if it stays longer before transportation. Carefully take note of the time of stool collection and indicate clearly on the CRF whether the time given was estimated by the caregiver or observed by the healthcare provider.

3.0 Sample log and registration

- 3.1 All samples collected from a participant MUST be logged in the study Sample Shipment Log, available in the ward/ study office.
- 3.2 Time of sample collection and transport to the lab must be recorded on the study Sample

4.0 References

Toto Bora Study Stool Sample Collection SOP
CHAIN Stool collection SOP

5.0 Document history

Version 1	Author	Approved by	Dated	SOP No:
1.01 CHAIN_PB- SAM_Stool collection	Robert Bandsma	Caroline Tigoi		CHN...

6.0 Site training record

CHAIN WHOLE STOOL COLLECTION SOP

All sites are required to maintain a master copy of this SOP that documents the site staff that have been trained on this SOP.

Document History				
Version No.	Trained staff initials	Signature of trained staff	Date	Trainer's Initials
1.01	KDT	Example row	1 st Jan 2016	DM

7.0 Appendices

CHAIN WHOLE STOOL COLLECTION SOP

7.1 Sample Shipment Log

SITE NAME:		STUDY NAME:			POINT OF ORIGIN:		
DESTINATION:		PI NAME:			DATE:		
Subject ID	Specimen Type*	Sample number	Barcode	Visit No**	Date Collected	Time collected	Comments

SHIPPED BY _____ DATE _____ (DD/MM/YYYY) TIME _____ TEMP: _____

RECEIVING _____ DATE _____ (DD/MM/YYYY) TIME _____ TEMP: _____

STORED BY _____ DATE _____ (DD/MM/YYYY) TIME _____

KEY

Visit Numbers:**

Visit Numbers:** **A0**-Admission; **A2**- Day 21; **A3**- Day 60; **D0**-Discharge; **RA** – Readmission

Specimen Type*: Stool (F1, F2), Blood (Plasma, Serum) or Rectal Swab (R1 and R2)

CHAIN WHOLE STOOL COLLECTION SOP

7.2 Sample Collection Schedule

Sample collection Schedule

Tube	Volumes				
	Admission	Discharge	D 21	D 60	Readmission
Time point code	AO	D0	D1	D2	RA
EDTA 1 (Purple)	1.5 ml		1.5 ml		1.5 ml
Serum 1 (Red)	1.5ml		1.5 ml		1.5 ml
CBC	2ml				
HIV RDT	1				
Malaria RDT	1				1
Rectal swabs	2	2	2	2	2
Whole stool	1	1	1	1	1

CHAIN WHOLE STOOL COLLECTION SOP

SOP AWARENESS LOG

I, the undersigned below, hereby confirm that I am aware that the accompanying SOP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SOP versions in fulfilment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
1.			
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